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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/006,088 | 12/05/2001 | John W. Sliwa JR. | 003-007-C5 | 2423 |

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| EXAMINER |
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PEFFLEY, MICHAEL F

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| ART UNIT | PAPER NUMBER |
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3739

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,088

Applicant(s)

SLIWA ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 92-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 92-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/21/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 21, 2004 has been entered.

It is noted that applicant's response of May 21, 2004 has overcome the 35 USC 101 and 35 USC 112 rejections. Applicant has amended claim 92 to recite that the loop structure is "adapted to be placed" around tissue to avoid the positive recitation of tissue (i.e. non-statutory subject matter).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the curved transducer having a generally cylindrical shape must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary,

the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 92-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to disclose a curved transducer having a generally cylindrical shape for defining the focal length and focal angle of the energy. Figures 59-61 appear to show a transducer having a curved surface, but the examiner was unable to locate a curved transducer having a generally cylindrical shape as now set forth in the claims.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker et al ('084) in view of the teaching of Maguire et al ('288).

It is noted that the Acker et al device has an earliest filing date of March 24, 2000 based on priority to Provisional Application No. 60/192,074. Applicant's earliest prior application which includes support for the subject matter set forth in the instantly pending claims is US Serial No. 09/614,991 filed July 12, 2000. Hence the Acker et al patent is deemed to have an earlier priority date. Similarly, Maguire et al ('288) has a priority date of May 16, 2000.

Acker et al disclose a device for ablating tissue which comprises a body (10) which forms a loop structure. A plurality of ablating elements (26) is located on the body, each ablating element comprising an emitter of focused ultrasound energy (col. 4, line 36+). Acker et al specifically teach that each element may have a separate focal length, and that the focal length may be varied through tissue (col. 4, lines 60-67). The only features not expressly taught by Acker et al are the specific focal length and focal angle created by a curved ultrasonic transducer.

It is the examiner's position that the particular focal length and focal angle employed by the device would be inherently related to the tissue being treated and would therefore be an obvious operating parameter associated with the system in a

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given procedure. More particularly, the location and thickness of the tissue being treated would govern the necessary operating parameters and one of ordinary skill in the art would obvious recognize the necessary operating parameters for the procedure. Further, Maguire et al disclose an analogous ultrasonic ablation catheter which employs a series of transducers for ablating tissue. In particular, Maguire et al teach that the ablation transducers (830 – Figure 19b) may be provided with a curved surface to adjust the focal length of the device for treating a particular depth of tissue. See also column 46, lines 24+ of the Maguire et al reference. It is noted that the Maguire et al transducer (830) does not appear to be “generally cylindrical”, but does have the same structure as the curved transducer shown in Figures 59-61 of applicant’s specification.

To have provided the Acker et al device with transducers having a curved face to provide a desired focal length for treating tissue to a specific depth would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Maguire et al.

Claims 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al (‘199) in view of the teachings of Sanghvi et al (‘692).

Jenkins et al discloses an ablation apparatus which includes a loop-shaped body having a plurality of ablation elements located thereon. Jenkins et al teach that the ablation elements are preferably RF electrodes, but also teach that the ablation elements may be ultrasonic transducers (col. 15, lines 20-26). Jenkins et al fail to disclose the specific type of ultrasonic transducers (i.e. focused).

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Sanghvi et al teach of the known use of focused ultrasonic transducers for the ablation of tissue within the body. In particular, the focusing of the transducer allows a particular tissue to be targeted at a particular depth. Also, the Sanghvi et al transducers are curved (Figure 2, surface 190) to control the focal length of the focused energy. The examiner again maintains that one of ordinary skill in the art would obviously recognize the necessary focal length and focal angle which would be associated with a given procedure. Further, it also seems apparent that the Sanghvi et al transducers which have a curved surface may also be generally cylindrical.

To have provided the Jenkins et al device with a plurality of focused ultrasound energy emitters having a curved surface to target specific tissue and tissue depths for treatment would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Sanghvi et al.

Response to Arguments

With respect to the Acker et al reference, applicant's arguments with respect to claims 92-95 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to the Jenkins et al and Sanghvi et al references, filed May 21, 2004 have been fully considered but they are not persuasive. The examiner maintains that Jenkins et al fairly teaches a catheter device having a plurality of ablation elements, which ablation elements may be ultrasonic transducers. Sanghvi et al discloses the particular type of transducer having a curved surface for controlling the focal length of the emitted ultrasonic energy. To have provided the

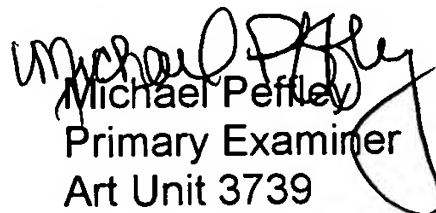
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Jenkins et al device with the Sanghvi et al transducers would have been an obvious modification to provide the Jenkins et al device with focused ultrasonic emitters for treating tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

Mp
July 22, 2004